Communications & Power Industries
communications & medical products divison

4 Oct 99

Dockets Management Branch (HFA - 305),
Food & Drug Administration,
5630 Fishers Lane, Room 1061,
Rockville,
MD, 20852,
USA.

Ref: Docket No. 98N-1215 (Proposed FDA Regulation for Foreign Establishment Registration and Listing).

Dear Sir/Madam,

As a Canadian manufacturer of medical devices (diagnostic X-ray generators and power supplies) exporting product into the United States, we offer the following comments regarding the above proposed regulations ammendment.
With regard to:

a) Device listing.
This is not seen as a significant issue and essentially is already done as part of the premarket approval process. We therefore have no objection to this.

b) Establishment registration.
With the assumption that the registration process is relatively simple, and there is no fee involved, we conclude that this should impose no significant financial burden on manufacturers. We also recognize the advantages for the FDA in having an integrated listing of all establishments, and therefore have no objections to this part of the proposal.

c) Identification of a US agent.
From our perspective this part of the proposal is unnecessary for Canadian-based manufacturers. The duties of such an agent seem rather vague, however if the intent is to improve communications between the FDA and manufacturers we feel that for Canadian-based manufacturers this would not necessarily be achieved. Direct contact with a US agent may be no easier than with a manufacturer's establishment anywhere in North America, and the introduction of a third party could in fact lead to delays and misinformation.
If the intent of the proposal is to provide FDA with timely and accurate access to a manufaturer's records, then we again believe that our geographical proximity already facilitates this in an effective and efficient manner.

98N-1215

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Additionally it is our opinion that this proposal could be contrary to the philosophy of NAFTA, when applied to Canadian establishments, by placing an additional cost of business on them that is not borne by US-based companies. Notwithstanding this it would appear that the FDA has an effective means of preventing unapproved devices from entering the US by means of its liason with US Customs, and through its current facility inspection process.

We consider that the existence of a US agent will not benefit the FDA a great deal, but will add considerably to the costs of small and medium size companies such as CPI Canada. These increased costs would almost certainly be reflected in the selling price of the product and thus increase the cost of health care in the US.

For the above stated reasons we do not consider this part of the proposal to be necessary or desirable.

Copies of these comments are provided to:

Two copies to FDA Dockets Management Branch at above address.

One copy to Canadian Embassy,
501 Pennsylvania Ave. N.W.,
Washington, D.C., 20001,
USA.
Attention: Ms. Birgit Mattiesen,
Commercial Officer.

One copy to Ontario Exports,
56 Wellesley St. W., 7th Floor,
Toronto,
Ontario M7A 2E4.
Attention: Debbie Walker,
Area Director,
US Healthcare.

On behalf of CPI Canada Inc.

Gary Spiller, QA Manager.

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